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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09 391 783	09/08/1999	JOHN J. BALDWIN	1073 008H	9069

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EXAMINER

BAKER, MAURIE GARCIA

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 02/26/2003

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/391,783	Applicant(s) Baldwin et al
Examiner Maurie G. Baker, Ph.D.	Art Unit 1639

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE THREE MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event however may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on Dec 9, 2002

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

4) Claim(s) 4-7 and 38-49 is/are pending in the application

4a) Of the above, claim(s) 5-7 and 42-49 is/are withdrawn from consideration

5) Claim(s) 40 and 41 is/are allowed.

6) Claim(s) 4, 38, and 39 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

 If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

- 1) Certified copies of the priority documents have been received.
- 2) Certified copies of the priority documents have been received in Application No. _____.
- 3) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1.5

4) Interview Summary (PTO-413) Paper No(s) _____

5) Notice of Informal Patent Application (PTO-152)

6) Other

DETAILED ACTION

Please note: The number of Art Unit 1627 has been changed to 1639. Please direct all correspondence for this case to **Art Unit 1639**.

1. The Response filed December 9, 2002 is acknowledged. Claims 4-7 and 38-49 are currently pending. All previous rejections are withdrawn in view of applicant's arguments in the Response of March 14, 2002.

Election/Restriction

2. Applicant's election of species as required in the last action is acknowledged. The specific compound elected is the compound shown on page 2 of the Response. Because applicant did not distinctly and specifically point out the supposed errors in the election of species, the election has been treated as an election without traverse (MPEP § 818.03(a)) with respect to the species.

3. Claims 5-7 and 42-49 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to non-elected species, there being no allowable generic claim (see applicant's Response, page 5 for claims reading on the elected species). Claims 4 and 40 are generic to the elected species and are included in the examination to the extent of the elected species as set forth by MPEP § 803.02, see below.

4. Applicant's specifically elected species (compound shown on page 2 of the Response) was searched and was not found in the prior art. Thus, the search was expanded to non-elected species which *were* found in the prior art, see rejection below.

Please note MPEP § 803.02 (emphasis added):

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. **The prior art search, however, will not be extended unnecessarily to cover all nonelected species.** Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

However, note that claims 40 and 41 are deemed to be **allowable** (see paragraph 15 below).

5. Therefore, claims 4, 38, 39, 40 and 41 are examined on the merits in this action.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 4, 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

The specification as originally filed does not provide support for the invention as now claimed. Claim 4 (on which claim 38 and 39 depend) recites a negative proviso for R^1/R^2 and R^6/R^7 . Applicant has not pointed to support for this limitation. In order for a negative limitation to be added to a claim, that particular limitation must be specifically recited in the specification. MPEP 2173.05(i): Any negative limitation or exclusionary proviso must have basis in the original disclosure. See *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), aff'd mem., 738 F.2d 453 (Fed. Cir. 1984). The mere absence of a positive recitation is not basis for an exclusion.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 4, 38 and 39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter

which applicant regards as the invention.

Claim 4 (on which claim 38 and 39 depend) recites several terms that are unclear and confusing. The terms "carboalkoxy", "di-loweralkylamido", "methylene dioxy" and the last term in the Markush group for R⁴ and R⁵ taken together are set forth using terminology that is not art-standard and a definition is not provided in the specification for the meaning of these terms. Note the following from MPEP 2173.02: If the scope of the invention sought to be patented cannot be determined from the language of the claims with a reasonable degree of certainty, a rejection of the claims under 35 U.S.C. 112, second paragraph is appropriate. *In re Wiggins*, 488 F.2d 538, 179 USPQ 421 (CCPA 1973).

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Mukai et al (Bull. Chem. Soc. Jpn., Vol. 60, June 1987, pp. 2163-2167).

The reference discloses compounds that read directly on those claimed.

Specifically see Figure 1, compounds denoted δ-Toc model, Tocol Model 1 and 7-tBu-Toc 2. Compounds δ-Toc model and 7-tBu-Toc 2 read on the compounds

of claim 4 when the claimed R groups as follows: R¹ = OH; R² = lower alkyl (specifically methyl and t-butyl, respectively); R⁶ and R⁷ = H; and R⁴ and R⁵ are both lower alkyl (methyl). Compound Tocol Model 1 of the reference reads on the compounds of claim 4 when the claimed R groups as follows: R¹ = OH; R² = H; R⁶ and R⁷ = H; and R⁴ and R⁵ are both lower alkyl (methyl).

12. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Gan et al (Huaxue Xuebao, Vol. 39 (7-8-9), 1981, pp. 777-792, Abstract only).

The reference discloses compounds that read directly on those claimed.

Specifically see Abstract compound denoted V and text where R group of reference compound is denoted as H. Compound V reads on the compounds of claim 4 when the claimed R groups as follows: R¹ = OH; R² = lower alkyl (ethyl); R⁶ and R⁷ = H; and R⁴ and R⁵ are both lower alkyl (methyl).

13. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Leyshon et al (WO 91/11749).

The reference discloses compounds that read directly on those claimed.

Specifically see Table 1 on pages 3-4, compounds denoted (II), (III) and (VIII). Compounds (II) and (VIII) read on the compounds of claim 4 when the claimed R groups as follows: R¹ = OH; R² = lower alkyl (t-butyl); R⁶ and R⁷ = H; and R⁴ and R⁵ are both lower alkyl (methyl). Compound (III) of the reference reads on the compounds of claim 4 when the claimed R groups as follows: R¹ = OH; R² = H; R⁶ and R⁷ = H; and R⁴ and R⁵ are both lower alkyl (methyl).

14. Claim 4 is rejected under 35 U.S.C. 102(b) as being anticipated by Miyano et al (US 4,665,203).

Note that for the purposes of this rejection, a group of -CO-Oalkyl is deemed to read on carboalkoxy. This term is confusing and not defined; see rejection under 35 USC 112, second paragraph above.

The reference discloses compounds that read directly on those claimed.

Specifically see Example 10 (compound in column 9, lines 60-68) and Example 27 (compound in column 19, lines 60-68). The compound of Example 10 reads on the compounds of claim 4 when the claimed R groups as follows: $R^1 = OH$; $R^2 =$ lower alkyl (propyl); R^6 and $R^7 = H$; R^4 is lower alkyl (methyl); and R^5 is substituted lower alkyl (where the substituent is carboalkoxy). The compound of Example 27 reads on the compounds of claim 4 when the claimed R groups as follows: $R^1 = OH$; $R^2 =$ lower alkyl (propyl); R^6 and $R^7 = H$; $R^4 = H$; and R^5 is substituted lower alkyl (where the substituent is carboalkoxy).

Status of Claims/Conclusion

15. Claims 40 and 41 are allowable over the prior art of record.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maurie Garcia Baker, Ph.D. whose telephone number is (703) 308-0065. The examiner can normally be reached on Monday-Thursday and alternate Fridays from 9:30 to 7:00.

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang, can be reached at (703) 306-3217. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Maurie Garcia Baker, Ph.D.
February 21, 2003



MAURIE GARCIA BAKER, Ph.D.
PRIMARY EXAMINER